

Institutional Biosafety Committee

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What is Biosafety?

*Science of
maintaining a broken
chain of infection*

What is an IBC?

- “Committee with experience and expertise to evaluate recombinant DNA research to identify potential risks to public health and the environment.”
- Functions may be expanded beyond those listed as each institution prefers.

IBC Development

- What is your scope?
- What will PIs submit to the committee for review?
- How will you proceed when protocols need to be reviewed?

Functions

- Review and approve rDNA activities
- Define containment levels
- Assess the facilities, procedures, practices, and training and expertise of personnel involved in rDNA

Functions

- Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements of the NIH Guidelines
- Notify the PO of the results of the IBC's review and approval

Functions

- Periodically reviewing rDNA research to ensure compliance with the NIH Guidelines
- Adopting emergency plans covering accidental spills and personnel containment resulting from rDNA

Responsibilities

- Review internal and external factors to determine if the risk for a project is acceptable to WRAMC
- Record meeting minutes
- Submit annual report to NIH
 - Roster/CVs

NIHG Applicability

- If any of the RDNA research is funded by NIH, then the Guidelines may be required
- Exemptions are given in Section III-F

NIHG Applicability

If NIHG are not required,
ensure the collaborator
understands the IBC will
be submitting to NIH
-Proprietary issues

NIHG

- No member of an IBC may review/approve a project in which he/she has an involvement (either directly or financial interest)

Protocol Review

What do you need to do
when reviewing a new
project?

Protocol Review

- Biohazardous Agent /
Material
- Host (workers, public)
- Environment

Biohazardous Material

- Pathogenicity(morbidity vs. mortality)
- Infectious Dose
- Concentration / Volume
- Stability
- Vaccine / treatment availability

Biohazardous Material

- Biohazard Potential
 - Biosafety Level 1 (BL1)
 - Biosafety Level 2 (BL2)
 - Biosafety Level 2* or 2+ (BL2* or BL2+)
 - Biosafety Level 3 (BL3)
 - Biosafety Level (BL4)

BL1

- Low Risk
- Not known to cause disease in healthy adult humans
- Examples: *Bacillus subtilis*, *E. coli*

BL2

- Agents know to cause human disease that can be moderately serious, and for which preventative or therapeutic interventions are often available
- Examples: Salmonella, Hepatitis, Giardia, Cladosporium

BL2

- Potential routes of entry are percutaneous, injection, ingestion, and direct contact with mucous membranes
- Access control biosafety manual, medical surveillance, biohazard sign, BBE, autoclave

BL3

- Indigenous or exotic with potential for infection following aerosol transmission
- Associated with serious or lethal human disease for which preventive or therapeutic interventions may be available

BL3

- Examples: TB, yellow fever, *Coxiella burnetii*, Venezuelan equine encephalitis
- Requires special facility design and special containment

BL2*/2 +

- Utilizing a BL2 facility with the addition of BL3 procedure, precautions, and PPE
- Example: HIV

BL4

- Dangerous/exotic agents that pose a high risk of life-threatening disease
- Preventive or therapeutic interventions are usually not

BL4

- Examples: Lassa fever virus, Ebola virus, tickborne encephalitis virus complex
- Numerous facility and PPE requirements

Biohazardous Material

- CDC Restricted Agent List
 - Numerous requirements
 - Must register with CDC

Host

- Health status (vaccinations, immune status, pregnancy)
- Training, experience, skills
- Medical surveillance
- Use of personal protective equipment
- Perceptions

Environmental

- Population density
- Medical support availability
- Weather conditions
- Perceptions
- Waste issues (internal)
- Facility Design (internal)

Containment

- Laboratory/Clinical Practices
- Safety Equipment
- Facility Design

Containment

- Primary
 - Biological safety cabinets
 - HEPA filtered enclosures
 - PPE
 - Sealed centrifuge rotors

Containment

- Secondary
 - Differential pressurization of work areas
 - HEPA filtered exhaust ventilation
 - Sterilization of effluent liquids

Biological Barriers

- Limit ineffectiveness of vector / vehicle (plasmid or virus) for specific hosts
- Limit dissemination and survival in the environment
 - Genetically design vectors to decrease probability of dissemination outside of

Emergency Preparedness

- Biological Emergency Response and Assistance Plan (BERAP)
 - Risk assessment summary
 - Address most probable events & worst case scenarios
 - Define responsibilities
 - Address risk communication
 - Outline procedures

Protocol Review

- Shipping / transportation
 - 42 CFR Part 72
 - WHO
 - USDA (animal pathogens)
- WRAMC requirements

Summary

- Risk assessment
 - Biological agent, Host, Environment
 - Consider social, political, ethical factors
- Answer all NIHG questions
- Vote and inform PI

Resources

- CDC
- NIH
- 42 CFR Part 72
- Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (WHO)
- OSHA (29 CFR 1910.1030)

Resources

- Primary Containment for Biohazards:
Selection, Installation, and Use of Biosafety Cabinets (CDC)
- Biosafety in Microbiologist and Biomedical Laboratories (BMBL), 4th